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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/904,536 | 07/16/2001 | Thomas J. Graddis | 3260.0028-01 | 3851 |
| 22852 | 7590 | 09/24/2004 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005 | | | SPECTOR, LORRAINE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 09/904,536 | Applicant(s) GRADDIS ET AL. | |
| | Examiner Lorraine Spector, Ph.D. | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004 and 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-43, 45, 52-55, 69-85, 88-93, 96-101 and 104-141 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-41, 69-80, 134 and 135 is/are allowed.
- 6) ☒ Claim(s) 111-132 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 33-43, 45, 52-55, 69-85, 96-101 and 104-141 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 42, 43, 45, 52-55, 81-85, 88-93, 96-101, 104-110, 133, 136-141 .

DETAILED ACTION

The rejection under 35 U.S.C. §112, first paragraph is withdrawn in view of applicants amendment and election.

Election/Restrictions

Applicant's election with traverse of the restriction requirement of 5/04 in the reply filed on 7/1/04 is acknowledged. The traversal is on the ground(s) that (a) the inventions are not independent and distinct as required by 35 U.S.C. §121, (b) the search of all inventions would not present a serious burden to the examiner, and (c) that applicants amendment did not necessitate the current restriction requirement. This is not found persuasive because with respect to point (a), the phrase "independent and distinct inventions in the statute has been historically treated by the Office as "independent or distinct inventions", see MPEP 802.01. In this case, the inventions are distinct, as they each require a separate search of the art with respect to enablement, as set forth in the requirement. Applicants assertion that "this is not the test to determine whether claims are distinct" is not persuasive. While the MPEP does not provide specific guidance for this fact situation, the Examiner has pointed out the reasons for the finding that the search in this case is burdensome. In fact, the Examiner attempted to search this case *prior* to making the requirement, and only made the requirement after determining that the search was burdensome. It is for this reason that point (b) above is also not persuasive. Finally, applicants third point is not germane. Restriction may be properly made at any time during prosecution at which the Examiner finds such necessary. In this case, the amendments filed 3/4/04 presented the claims in a fashion that required extensive extra searching in order to properly consider enablement of the claimed inventions, which searching proved to be burdensome, for reasons cited above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 42, 43, 45, 52-55, 81-85, 88-93, 96-101, 104-110, 133 and 136-141 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a

nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/1/2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 111-132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 111 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no connection between step (a) and step (b). It cannot be determined how the administration relates to the transplant step, and in what fashion. Similarly, claim 112 is indefinite as it is not clear at what point in the process the administration is to occur. Additionally, it is not clear how administering radiation and/or chemotherapy is part of a process of transplanting hematopoietic stem cells.

Claim 122 is indefinite as it is not clear whether the cells of part (b) of the claim are the same cells as in part (a) of the claim; amendment of “transplanting hematopoietic” to read – transplanting *said* hematopoietic-- would be remedial.

Claim 123 is indefinite as it is not clear at what point in the process the administration is to occur. Additionally, it is not clear how administering radiation and/or chemotherapy is part of a process of transplanting hematopoietic stem cells.

The remaining claims are rejected for depending from an indefinite claim.

Advisory Information

Claims 33-41, 69-80 and 134-135 are allowable.

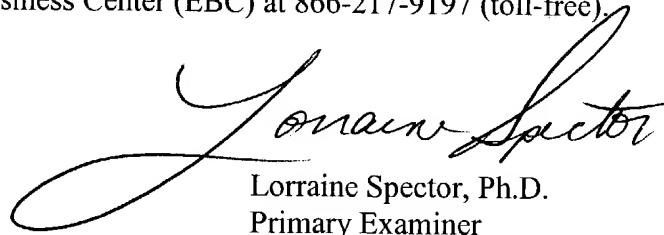
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lorraine Spector, Ph.D.
Primary Examiner